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EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 12/27/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/921,013

Applicant(s)

Yang et al.

Examiner

Vera Afremova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct 23, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above, claim(s) 12-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1
- 4) ☐ Interview Summary (PTO-413) Paper No(s)
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other

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### **DETAILED ACTION**

Claims 1-23 are pending.

#### ***Election/Restriction***

Applicants' election with traverse of the Group I invention (claims 1-11), drawn to a microbial strain KCTC 0687BP, to a method for producing polysaccharide by culturing the strain KCTC 0687BP and to a product obtained by culturing the strain KCTC 0687BP, in the Paper No. 6 filed 10/23/2002 is acknowledged. The traversal is on the ground(s) that there is no burden in searching the entire claimed subject matter. However this is not found persuasive because the claimed methods and compositions are of a different scope and the references which would be applied to one method/composition would not necessarily anticipate or render obvious the other method/composition. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exists.

For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL.

Claims 12-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

**Claims 1-11 are under examination in the instant office action.**

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***Deposit***

The deposit requirement for the microbial strain *Enterobacter sp.* (SSYL) KCTC 0687BP is met in the Papers No. 1 filed 7/21/2001 (the deposit declaration, the deposit receipt and the specification, page 5).

***Claim Rejections - 35 USC § 112***

***Indefinite***

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 are indefinite in the recitation of identifying characteristics of "an isolated microorganism" deposited in the collection KCTC under accession number 0687BP since it is unclear which characteristics of the "isolated microorganism" are intended. The fact that the claimed product might be obtained from KCTC does not indicate any microbial characteristics. The phrase "isolated" in the context of the instant claims 1 and 2 is confusing and indefinite because it is uncertain whether only one microbial cell from the whole deposit biological material is claimed and what are criteria for isolating this one and only cell from the deposited material. The suggested language is following, for example: "A biologically pure culture of *Enterobacter sp.* having all of the identifying characteristics of *Enterobacter sp.* SSYL deposited under accession number KCTC 0687BP".

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Claims 3-7 and 11 are rendered indefinite by the phrase "method of claim 1" because the claim 1 is drawn to a product and it does not set forth any steps of a method for isolating and/or culturing an isolated microorganism. The limitations of claims 3-7, for example: "the culture medium" or "culturing" do not find the antecedent basis in the claim 1. In the instant office action claims 3-7 are interpreted as depending on the method of claim 2. The subject matter of claim 11 is interpreted as a product obtained by the method of claim 2.

Claim 9 is indefinite, confusing and fails to further limit the claimed method. It is uncertain what is "a mixture comprising the exopolysaccharide" (claim 9, line 3) and how this mixture is obtained. Claim 9 appears to further limit the step of removing cells (claim 9, line 1) in the method of claim 8 but it is also encompasses precipitating and dissolving the exopolysaccharide. Thus, it is uncertain whether the claim 9 is an alternative method for producing exopolysaccharide.

Claim 10 recites the limitation the "separated" exopolysaccharide in the method according claim 8. There is insufficient antecedent basis for this limitation in the claim 8 which recites "dialyzing" and "isolation".

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 4,806,636 [A] or US 5,360,737 [B].

The claim is drawn to a particular strain deposited in KCTC under accession number 0687BP.

US 4,806,636 [A] discloses three particular strains belonging to the genus of *Enterobacter* and having the ATCC accession numbers 53017, 29004 and 12868. The disclosed strains are capable to produce exopolysaccharides. See abstract.

US 5,360,737 [B] discloses a particular strains belonging to the genus of *Enterobacter* and having the accession number FERM BP-1529. The disclosed strain is capable to produce exopolysaccharide. See abstract.

The cited patents disclose microbial strains which appear to be identical to the presently claimed strain since they belong to the same genus of *Enterobacter* and they are capable to produce exopolysaccharides as intended for the applicants' strain (see abstract, page 24). Consequently, the claimed strain appears to be anticipated by the cited patents.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganisms with regard to some unidentified characteristics, the differences between that

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which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103. Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the references, especially in the absence of evidence to the contrary.

***Claim Rejections - 35 USC § 103***

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,806,636 [A] and US 5,360,737 [B] taken with Shimada et al. [IDS-2].

Claims are directed to a microbial strain KCTC 0687BP, to a method for producing an exopolysaccharide by culturing the strain KCTC 0687BP and to a crude preparation obtained by culturing the strain KCTC 0687BP. Some claims are further drawn to the use of particular medium components including glucose or lactose, and to the use of particular temperature or aeration conditions including 25°C to 38°C and agitation speed 150-500 rpm in the method for producing exopolysaccharide. Some claims are further drawn to isolating the exopolysaccharide by removing cells from the whole culture and by dialyzing, precipitating, dissolving and lyophilizing the exopolysaccharide.

The cited patent US 4,806,636 [A] teaches microbial strains ATCC 53017, ATCC 29004 and ATCC 12868 belonging to the genus of *Enterobacter*, a method for producing an

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exopolysaccharide by culturing these strains and a crude preparation obtained by culturing these strains (abstract). It also teaches the use of medium components including glucose (col. 6, line 10), the use of temperature 30°C and aeration of the culture by agitation in a shaker in the method for producing exopolysaccharide (col.6, lines 29-31). It also teaches isolation of the exopolysaccharide by removing cell pellet from the resulting culture mixture and by precipitating, dissolving and drying the exopolysaccharide (col. 6, example 4).

The cited patent US 5,360,737 [B] teaches microbial strain FERM BP-1529 belonging to the genus of *Enterobacter*, a method for producing an exopolysaccharide by culturing this strain and a crude preparation obtained by culturing this strain (abstract). It also teaches the use of medium components including lactose (col. 4, line 16), the use of temperature 30°C and aeration by shaking (col.4, line 14) in the method for producing exopolysaccharide (col. 4, lines 8-25). It also teaches isolation of the exopolysaccharide by centrifugal separation in order to remove cells from the resulting culture mixture and by precipitating and drying the exopolysaccharide (col. 4, lines 19-23).

Thus, the cited patents US 4,806,636 [A] and US 5,360,737 [B] teach the use of microbial strains which are substantially similar, if not identical, to the presently claimed strain in the method for producing exopolysaccharides comprising similar steps including the use of the same medium components and temperature conditions as presently claimed. Therefore, the product obtained by culturing the cited strains is reasonably expected to be substantially similar to the presently claimed product, particularly in view that the reference by Shimada et al. [IDS-2]

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teaches that representatives of the genus *Enterobacter* are known to be capable to produce polysaccharides and they have been used for polysaccharide production (page 113, col. 1, par. 2).

The cited patents US 4,806,636 [A] and US 5,360,737 [B] are lacking disclosure about the use of particular aeration flow provided by the shaker agitation speed of 150-500 rpm and about dialyzing step in the method of polysaccharide production. However, the reference by Shimada et al. [IDS-2] teaches the use a rotary shaker at a speed 160 rpm (page 113, col. 2, last paragraph) and the dialyzing step (page 114, col.1, par. 2) in the method of polysaccharide production by culturing microorganisms belonging to the genus of *Enterobacter*.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to obtain and to use microorganisms belonging to the species of *Enterobacter* in the method of polysaccharide production with a reasonable expectation of success in isolating polysaccharide by culturing the microorganisms belonging to the species of *Enterobacter* as taught by all cited references {US 4,806,636 [A], US 5,360,737 [B] and Shimada et al. [IDS-2]}. Although the cited patents US 4,806,636 [A] and US 5,360,737 [B] are lacking the disclosure of a particular strain KCTC 0687BP in the method for producing polysaccharide, there is a reasonable believe and expectation in success in isolating polysaccharides by culturing the microorganisms belonging to the species of *Enterobacter* as adequately demonstrated by the teaching of Shimada et al. [IDS-2]. One of skill in the art would have been motivated to modify or to adjust the culture conditions according to the growth requirement of a particular microbial strain or of a particular species of *Enterobacter* for the

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expected benefit in maximizing yields of the final products including polysaccharide preparations. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova

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December 24, 2002.

VERA AFREMOVA

PATENT EXAMINER

